REMARKS

Reconsideration of the application as amended is respectfully requested.

Status of the Claims

Claims 1-4, 7, and 9-31 are currently pending in this application. Claim 17 is being presented herein in amended form from its previously presented form. New claims 21-27 and 29-30 are being re-presented herein. Claims 5-6 and 8 have been previously cancelled.

Discussion of the Amendments to the Claims

The claims have been amended to point out more particularly and to claim more distinctly the subject invention. In particular, claim 17 has been amended to recite that a buffered phosphate is added to the composition. This amendment is non-narrowing in scope. Support for this amendment can be found in the instant specification at, for example, col. 6, lines 11-13. No new matter has been added by way of this amendment to the claims.

Discussion of Status Identifiers with Regard to Claims 21 -27 and 29-30

The Examiner alleges that "claims 21-27 and 29-30 appear to have improper status identifiers because these claims were 'new' in the October 25, 2004 amendment." In this regard, the Examiner states that the appropriate status identifier would be "previously presented."

Referring to M.P.E.P. § 1453, nowhere is it indicated that a previously presented "new" claim must include the status identifier "previously presented." In any event, in an effort to advance prosecution, Applicants have deleted the status identifier "new" from claims 21-27 and 29-30 in the listing of claims provided herein, thereby placing those claims in the form exemplified for "new" claims in M.P.E.P. § 1453.

Response to the Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 17, 18, and 28 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner alleges that claims 17 and 18 "contradict claim 13 that requires 'a biodegradable composition having an acidic pH' contained in the pores." (Office Action, page 2). Moreover, the Examiner alleges that claim 28 contradicts base claim 13. In this regard, the Examiner alleges that claim 28 requires a pH-adjusted solution, while claim 13 requires an acidic solution. For the reasons set forth below, Applicants respectfully traverse the rejection under 35 U.S.C. §112, second paragraph.

As amended, claim 17 now recites that a buffered phosphate is added to the composition. Thus, claim 13 is directed to an implantable prosthesis that has pores that contain a solution of a biodegradable composition having an acidic pH, while claims 17 and 18 are directed to embodiments of that same prosthesis wherein a buffered phosphate is added to the composition. In view of the amendment to claim 17, it is respectfully submitted that claims 17 and 18 do not contradict claim 13. Accordingly, it is respectfully submitted that claims 17 and 18 are definite.

Turning to claim 28, Applicants respectfully request reconsideration of that claim. In particular, one of ordinary skill in the art would appreciate that claim 13 is directed to a prosthesis having pores that contain a solution of a biodegradable composition having an acidic pH, while claim 28 is directed to an embodiment of that same prosthesis wherein the acidic solution is pH-adjusted to a pH of about 7.4. Accordingly, it is respectfully submitted that claim 28 is definite.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Response to the Rejection under 35 U.S.C § 251

Claims 1-4, 7, and 9-31 stand rejected under 35 U.S.C. § 251 as allegedly being an improper recapture of broadened subject matter surrendered in the application for the patent upon which the present reissue is based. Specifically, the Examiner states that during the pendency of U.S. Application Serial No. 08/289,790, which issued as U.S. Patent No. 5,665,114, the following limitations were added to overcome a prior art rejection: "filled with [a] fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4." (Office Action, page 3). The Examiner then concludes that Applicants are improperly attempting to recapture subject matter previously surrendered. In support of the rejection, the Examiner alleges that Applicants' standard for recapture is not proper. Applicants respectfully request reconsideration of the rejection under 35 U.S.C. § 251.

As noted in the Amendment and Response to Office Action that was filed on April 11, 2005 (which is incorporated herein by reference), reissue claims that are broader in certain respects but narrower in other respects may avoid the effect of the recapture doctrine. Thus, contrary to the Examiner's assertion, a patentee can, therefore, obtain a reissue claim where that claim varies materially from the claim originally surrendered, even where it omits a limitation added during prosecution. *Donald S. Chisolm, Chisolm on Patents*, §15.03 [2] [e] (1999).

Original claim 1, which was subsequently amended to include limitations mentioned by the Examiner, recited the following:

> **An implantable member for use in repair or replacement with a body comprising an expanded polytetrafluoroethylene surface having pores present in its wall structure wherein said pores contain a solid insoluble biocompatible, biodegradable material of natural origin.**

Applicants do not dispute that the limitations "filled with a fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4" were specifically

added to original claim 1 during prosecution. However, as discussed below, presently pending claims 1-4, 7, and 9-31 do not attempt to recapture subject matter previously surrendered.

Discussion of Claims 1-4, 7, 9-12, 22-23, and 26

Presently pending claim 1 recites the following:

> **An implantable member for use in repair or replacement within a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, *said pores filled with a solid precipitate of a material of natural origin formed in situ from a solution that is pH-adjusted within said pores*.**

As highlighted above, presently pending claim 1 contains the limitation that the pores are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. Clearly, presently pending claim 1 is materially different from claim 1, as originally presented in the prior application, which does not contain such a limitation. Moreover, as claims 2-4, 7, 9-12, 22-23, and 26 depend from claim 1 (either directly or indirectly), those claims also are materially different from claim 1 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 1-4, 7, 9-12, 22-23, and 26 are properly submitted in the reissue application.

Discussion of Claims 13-20 and 28

Presently pending claim 13, as amended herein, recites the following:

> **An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils, wherein *a solution of a biodegradable composition having an acidic pH***

> ***is contained within said pores, wherein said biodegradable composition is capable of forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.***

As highlighted above, presently pending claim 13, as amended herein, contains the limitation that the pores contain a solution of a biodegradable composition having an acidic pH. Moreover, amended claim 13 contains the limitation that the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. In view of these limitations, presently pending claim 13, as amended herein, is materially different from claim 1 as originally presented in the prior application. As claims 14-20 and 28 depend from claim 13 (either directly or indirectly), those claims also are materially different from claim 13 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 13-20 and 28 are properly submitted in the reissue application.

Discussion of Claims 21, 24-25, and 27

Presently pending claim 21 recites the following:

> **An implantable member for use in repair or replacement within a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, *said pores substantially filled with a solid precipitate of a material of natural origin formed in situ from a solution that is pH-adjusted within said pores*.**

As highlighted above, presently pending claim 21 contains the limitation that the pores are substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within said pores. In view of this limitation, presently pending claim 21 is materially different from claim 1 as originally presented in the prior application. As

claims 24-25 and 27 depend (either directly or indirectly) from claim 21, those claims also are materially different from claim 1 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 21, 24-25, and 27 are properly submitted in the reissue application.

Discussion of Claims 29-31

Presently pending claim 29 recites the following:

An *intermediate* implantable member for use in repair or replacement within a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils, with pores present between said nodes and said fibrils, *said pores filled with an acidic fluid.*

As highlighted above, pending claim 29 recites an intermediate implantable member having pores that are filled with an acidic fluid. In view of this recitation, presently pending claim 29 is materially different from claim 1 as originally presented in the prior application. As claims 30-31 are dependent upon claim 29 (either directly or indirectly), those claims also are materially different from claim 1 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 29-31 are properly submitted in the reissue application.

In view of the foregoing, the recapture doctrine is inapplicable in the case at hand. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 251.

Discussion of the 35 U.S.C. § 102(b) Rejection in View of Kaehler With Regard to Claims 1-4, 7, and 21-25

It is Applicant's understanding that claims 1-4, 7, and 21-25 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kaehler et al., *Journal of Vascular Surgery*, 9(4) (April 1989) (hereinafter "Kaehler").[1] Although the Examiner acknowledges that the method used to form the graft of Kaehler is different that the method of the present invention, the Examiner nevertheless concludes that claims 1-4, 7, and 21-25 lack novelty in view of Kaehler. In particular, the Examiner, citing M.P.E.P. §2113, alleges the following:

> "The claims require that the implantable member of ePTFE contains a biodegradable composition of natural origin in its pores. On page 536, Kaehler teaches forcing type I and III collagen through the graft repeatedly until it was almost impossible to force any more through; see page 536, first full paragraph. This collagen is the same as the "solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores" because it is collagen that is pH adjusted outside the pores (see *supra*) and then forced through the pores. Even though a different method is used, the same product results because pH adjusted collagen ends up in the pores of the same substrate as claimed."

The rejection under 35 U.S.C. §102(b) is respectfully traversed for the reasons set forth below.

For the sake of accuracy, Applicants note that claims 1-4, 7, and 21-25 do not recite the phrase "biodegradable composition of natural origin." Rather, those claims all recite a solid precipitate.

In that regard, the only process language appearing in claims 1 and 21 pertains to the formation of that solid precipitate. The solid precipitate, however, is only one aspect of the implantable members recited therein. Indeed, the implantable member recited in claims 1-4,

[1] The Examiner asserts that the claimed invention is "at least obvious in view of Kaehler alone." (Office Action, page 5). However, a rejection under 35 U.S.C. § 103(a) has not been made in view of Kaehler alone. In any event, Applicants submit that Kaehler alone does not render the subject invention obvious.

7, and 22-23 and the implantable member recited in claims 21 and 24-25 both include several structural limitations. In particular, those implantable members must have an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between the nodes and fibrils. Moreover, the presence of the precipitate in the pores itself constitutes a structural limitation. Accordingly, Applicants respectfully submit that claims 1-4, 7, and, 21-25 are not product-by-process claims in the traditional sense.

Moreover, even assuming *arguendo* that the aforementioned claims are properly termed "product-by-process" claims that fall within the scope of MPEP § 2113, the process language appearing in those claims is necessary to describe the precipitate, i.e., to clarify the nature of the precipitate. Accordingly, Applicants respectfully submit that such language must be given patentable weight. *See In re Thorpe*, 777 F.2d 695, 697, 227 U.S.P.Q. 964, 965-966 (Fed. Cir. 1985). ("The practice and governing law have developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made.)

Nonetheless, implantable members having pores substantially filled or filled with a solid precipitate *in situ* from a solution that is pH-adjusted within the pores creates a distinctly different graft than that disclosed by Kaehler. Kaehler fails to teach each and every element of claims 1-4, 7, and 21-25 and, therefore, fails as a § 102(b) reference. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b) with regard to claims 1-4, 7, and 21-25.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kaehler in View of the Hoffman '977 Patent

Claims 9-10 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kaehler in view of U.S. Patent No. 5,197,977 (hereinafter "the Hoffman '977 patent"). In particular, the Examiner predicates the rejection on the alleged teaching of Kaehler as set forth by the

Examiner with regard to the rejection under 35 U.S.C. § 102(b). Although the Examiner acknowledges that Kaehler fails to disclose the use of a pharmacological agent as claimed, the Examiner nevertheless contends that it would have been obvious to include a pharmacological agent in the Kaehler implant in view of the Hoffman '977 patent. For the reasons set forth below, this rejection is traversed.

As claim 9 depends directly from claim 1, and as claim 10 depends from claim 9, those claims are both directed to an implantable member having pores that are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. However, there is no disclosure in Kaehler of precipitating a material of natural origin out of a solution *in situ* by means of pH-adjustment of the solution within the pores. Nor is there any teaching or suggestion in Kaehler of precipitating a material of natural origin out of a solution *in situ* by means of pH-adjustment of the solution within the pores. (See Declaration of Gary Loomis, ¶19).[2] Indeed, Kaehler teaches away from doing the same as Kaehler is merely concerned with coating the surfaces of PTFE grafts and actually discloses adjusting the pH of the collagen solution referenced therein prior to application of the solution onto the graft. (See Declaration of Gary Loomis, ¶7).

The Hoffman '977 patent was cited merely for its disclosure of pharmacological agents. The Hoffman '977 patent nowhere discloses, teaches or suggests an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores of the graft. (See Declaration of Gary Loomis, ¶19). Therefore, the Hoffman '977 patent fails to cure the deficiencies of Kaehler. Moreover, in view of the fact that the Hoffman '977 patent is directed to textile grafts and not PTFE grafts, one of ordinary skill in the art would not even be motivated to combine the disclosure of the Hoffman '977 patent with the disclosure of the Kaehler reference. (See id.). In view of the foregoing, claims 9 and 10 are not obvious in view

[2] The Declaration of Gary Loomis was submitted along with the Amendment and Response to Office Action filed on April 11, 2005.

of the teachings of Kaehler in combination with the Hoffman '977 patent. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection with regard to claims 9 and 10 based on this combination of references.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kaehler in View of Tran

Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kaehler in view of Tran and Walt, *Journal of Colloid and Interface Science*, 132(2) (October 15, 1989) (hereinafter "Tran"). In particular, the Examiner predicates the rejection on the alleged teaching of Kaehler as set forth by the Examiner with regard to the rejection under 35 U.S.C. § 102(b). Although the Examiner acknowledges that Kaehler fails to teach modifying a substrate to enhance its hydrophilic character by subjecting the polytetrafluoroethylene to plasma deposition, the Examiner nevertheless contends that it would have obvious to use plasma deposition to pretreat the graft of Kaehler. For the reasons set forth below, this rejection is traversed.

As claim 11 depends directly from claim 1, and as claim 12 depends from claim 11, those claims are directed to an implantable member having pores that are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. However, as discussed above, Kaehler fails to disclose an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores of the graft. Nor is there a teaching or suggestion to do so. (See Declaration of Gary Loomis, ¶7). Indeed, Kaehler is merely concerned with coating the surfaces of PTFE grafts and actually discloses adjusting the pH of the collagen solution referenced therein prior to application of the collagen solution onto the graft. (See id.). As such, Kaehler actually teaches away from precipitating a material of natural origin within the pores of a graft.

Tran was cited only for its disclosure with regard to plasma deposition. Tran nowhere discloses, teaches or suggests an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores of the graft. (See id.). Therefore, Tran fails to cure the deficiencies of Kaehler as a reference. In view of the foregoing, claims 11 and 12 are not obvious in view of the teachings of Kaehler in combination with Tran. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection with regard to claims 11-12 based on this combination of references.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kaehler in View of Alonso

Claims 26-27 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kaehler et al. in view of U.S. Patent No. 5,037,377 (hereinafter "Alonso"). In particular, the Examiner predicates the rejection on the alleged teaching of Kaehler as set forth by the Examiner with regard to the rejection under 35 U.S.C. § 102(b). Although the Examiner acknowledges that Kaehler fails to teach the pH of the phosphate buffer as claimed, the Examiner nevertheless contends that it would have been obvious to use a phosphate buffer having a pH of 7.4 in view of the Alonso reference.

As claim 26 depends directly from claim 1, claim 26 is directed to an implantable member having pores that are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. Furthermore, as claim 27 depends directly from claim 21, claim 27 is directed to an implantable member where the pores of an expanded polytetrafluoroethylene substrate are substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores.

However, there is no disclosure, teaching or suggestion in Kaehler of an implantable prosthesis that includes pores that contain a solution of a biodegradable composition having an

acidic pH, wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. (See Declaration of Gary Loomis, ¶17). Moreover, as discussed above, there is no disclosure or suggestion in Kaehler of an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled or substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. (See Declaration of Gary Loomis, ¶¶ 7 and 13).

Alonso was merely cited for its disclosure with regard to phosphate buffer. There is no disclosure, teaching or suggestion in Alonso, however, of an implantable prosthesis where the pores of an expanded polytetrafluoroethylene substrate contain a biodegradable composition having an acidic pH, much less a disclosure, teaching or suggestion of such an implantable prosthesis where such a biodegradable composition is capable of forming a precipitate at selected conditions of temperature and pH to form an insoluble substrate for cellular attachment. Moreover, there is no disclosure, teaching or suggestion in Alonso of an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled or substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. (See Declaration of Gary Loomis, ¶19). Therefore, Alonso fails to cure the deficiencies of Kaehler as a reference.

In view of the foregoing, claims 26-27 are not obvious in view of the teachings of Kaehler in combination with Alonso. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection with regard to claims 26-27 based on this combination of references.

Discussion of the 35 U.S.C. § 102(b) Rejection in View of Kaehler With Regard to Claims 13-18 and 29-31

Claims 13-18 and 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kaehler. Applicants respectfully traverse the rejection for the reasons set forth below.

The Examiner provides no reasoning in support of the rejection and, as such, it is unsubstantiated. Moreover, for the reasons discussed in the Amendment and Response to Office Action filed on April 11, 2005, Kaehler does not anticipate claims 13-17 or claims 29-31. Nor does Kaehler anticipate claim 18. Indeed, it cannot be said that Kaehler discloses an intermediate implantable member where the pores in an expanded polytetrafluoroethyene substrate are filled with an acidic fluid (as required by claims 29-31). Moreover, it cannot be said that Kaehler discloses an implantable prosthesis where a solution of a biodegradable composition having an acidic pH is contained within the pores and is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment (as required by claims 13-18). Accordingly, Applicants respectfully submit that the anticipation rejection with regard to claims 13-18 and 29-31 is improper and should be withdrawn.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kodama in view of Kaehler or the Hoffman '977 Patent

In the alternative to the rejection with regard to claims 13-18 and 29-31 in view of Kaehler alone, claims 13-18 and 29-31 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view U.S. Patent No. 5,028,597 (hereinafter "Kodama") in view of Kaehler or the Hoffman '977 patent. Applicants respectfully traverse the rejection for the reasons set forth below.

Kodama is directed to an antithrombogenic material having an expanded polytetrafluoroethylene base having a collagen layer provided on the surface thereof. Contrary

to the Examiner's contention, it cannot be said that Kodama discloses an implantable prosthesis where a solution of a biodegradable composition having an acidic pH is contained within the pores and is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment (as required by claims 13-18).

Moreover, there is no disclosure of an implantable member where the pores in an expanded polytetrafluoroethyene substrate are filled with an acidic fluid (as required by claims 29-31). Kodama discloses no more than submerging an ePTFE tube in an aqueous collagen solution. Given the hydrophobic nature of ePTFE and the tortuous nature of the node and fibril structure, one of ordinary skill in the art would not expect the pores of the ePTFE to be filled with the aforementioned solution in which the ePTFE was submerged.

As regards Kaehler and the Hoffman '977 patent, those references fail to overcome the deficiencies of Kodama. In particular, neither of those references discloses an implantable prosthesis where a solution of a biodegradable composition having an acidic pH is contained within the pores and is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment (as required by claims 13-18). Moreover, neither of those references discloses an implantable member where the pores in an expanded polytetrafluoroethyene substrate are filled with an acidic fluid (as required by claims 29-31).

In view of the foregoing, claims 13-18 and 29-31 are not obvious in view of the teachings of Kodama in combination with the Hoffmann '977 patent or Kaehler. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection with regard to claims 13-18 and 29-31 based on this combination of references.

Discussion of the Rejection Under 35 U.S.C. § 103(a) with Regard to Claims 19-20

Claims 19-20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kodama, the Hoffmann '977 patent, and Kaehler as applied to claims 13-18 and 29-31 above in further view of the Hoffmann '977 patent.[3] Although the Examiner acknowledges that Kodama fails to disclose the use of a pharmacological agent, the Examiner nevertheless alleges that it would have been obvious to use a pharmacological agent in view of the Hoffmann '977 patent.

As claims 19-20 depend from claim 13 (either directly or indirectly), those claims directed to an implantable prosthesis that includes a body of expanded polytetrafluoroethylene having pores that contain a solution of a biodegradable composition having an acidic pH, wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. As discussed above, there is no disclosure, teaching or suggestion in any of Kodama, the Hoffmann '977 patent, or Kaehler of such an implantable prosthesis. Accordingly, the Hoffmann '977 patent does not remedy the deficiencies of Kodama or Kaehler.

In view of the foregoing, claims 19-20 are not obvious in view of the teachings of Kodama in combination with the Hoffmann '977 patent or Kaehler in further view of Alonso. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection with regard to claims 19-20 based on this combination of references.

[3] The Examiner lists the Hoffmann '977 patent twice with regard to the rejection of claims 19-20 under 35 U.S.C. § 103(a).

Discussion of the Rejection Under 35 U.S.C. § 103(a) With Regard to Claim 28

Claim 28 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kodama, the Hoffmann '977 patent, and Kaehler as applied to claims 13-18 and 29-31 above, and further in view of Alonso. Although the Examiner acknowledges that Kodama fails to teach the pH of the phosphate buffer as claimed, the Examiner nevertheless contends that it would been obvious to use a phosphate buffer having a pH of 7.4 in view of the Alonso reference.

As claim 28 depends from claim 13, claim 28 is directed to an implantable prosthesis that includes a body of expanded polytetrafluoroethylene having pores that contain a solution of a biodegradable composition having an acidic pH, wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. As discussed above, there is no disclosure, teaching or suggestion in any of Kodama, the Hoffmann '977 patent, or Kaehler of such an implantable prosthesis. Moreover, Alonso does not disclose an implantable prosthesis that includes a body of expanded polytetrafluoroethylene having pores that contain a solution of a biodegradable composition having an acidic pH, wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.

In view of the foregoing, claim 28 is not obvious in view of the teachings of Kodama in combination with the Hoffmann '977 patent or Kaehler in further view of Alonso. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection with regard to claim 28 based on this combination of references.

Additional Comments

Applicants respectfully submit that the Examiner has made certain inaccurate characterizations concerning the Declaration of Gary Loomis. Applicants respectfully submit that the declaration has not been afforded the weight and consideration to which it is entitled pursuant to M.P.E.P. § 716.01(c).

Concluding Remarks

The claims are believed to be allowable over the art and the application in good and proper form for allowance. The Examiner is invited to contact the undersigned if he has any questions regarding this submission or, if in his opinion, a teleconference call would expedite prosecution of the subject application.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,

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